



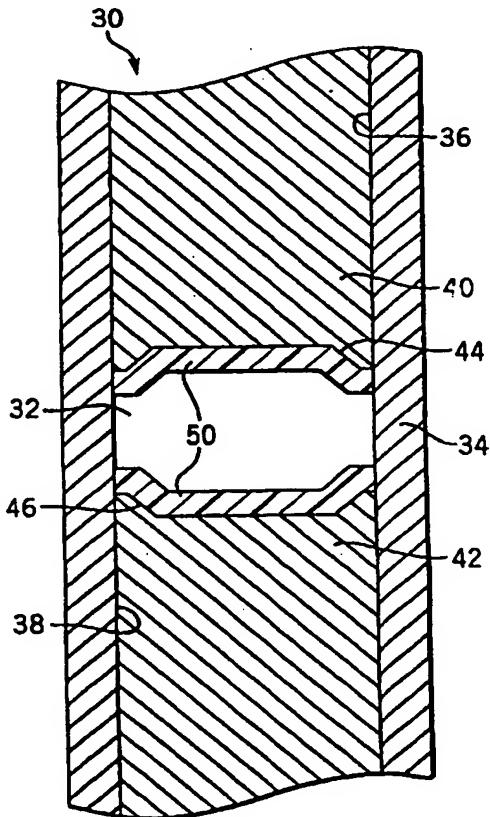
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(54) Title: IMPROVED DIE PUNCH AND TIP ASSEMBLY FOR FORMING COMPRESSION DOSAGE UNITS

(57) Abstract

A die punch apparatus forms compression tablets from tableting feedstock. The die punch apparatus includes a die punch and a removable die punch tip assembly. The die punch tip assembly includes a die punch body and a feedstock contacting member (50) formed thereon. The feedstock (11) contacting member is formed of resiliently compressible material for resilient engagement with the tableting feedstock (11) upon compression of the tableting feedstock into the tablet. Such resilient engagement permits release of feedstock from the feedstock contacting member (50).



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**IMPROVED DIE PUNCH AND TIP ASSEMBLY
FOR FORMING COMPRESSION DOSAGE UNITS**

CROSS REFERENCE TO RELATED APPLICATION:

This is a continuation-in-part of U.S. Patent Application Serial No. 09/076,416 filed May 12, 1998 which is incorporated by reference herein..

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FIELD OF THE INVENTION:

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The present invention relates generally to a die punch for forming compression dosage units, more specifically, tablets from tableting feedstock. More particularly the present invention relates to an improved die punch, die punch tip assembly and a method for constructing such a die punch where the formed tablet and residual feedstock is readily released from the die punch tip.

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BACKGROUND OF THE INVENTION:

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Dosage units in the form of tablets are typically prepared by compressing a tableting feedstock into a tablet configuration. The tableting feedstock may be a formulation containing a medicinal substance or drug and other ingredients such as excipients which are selected for properties which enhance the production and use of the tablet.

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One of the most common techniques to form a dosage unit such as tablet is by direct compression. Direct compression usually involves use of a tableting feedstock, which is a powdered blend of active ingredients with suitable excipients. Tableting processes using direct compression typically include the use of a machine which provides one or more sets of opposed upper and lower die punches and a die cavity positioned between the punches. The tableting feedstock is retained within the die cavity between the upper and lower die punches and the die punches are movable towards one another, or the upper die punch is moved towards the lower die punch within the cavity to compress the tableting feedstock into a tablet between the die punches. The tablet generally takes the shape and configuration defined by the opposed facing surfaces of the upper and lower die punches and the walls of the die cavity. An example of one such tableting process is shown and described in commonly assigned U.S. Patent No. 5,648,033. This

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reference is directed to an apparatus and method for forming a tablet from tableting feedstock which includes a die having an elongated cavity for receiving the feedstock. Two die punches which face each other are movably positioned within the cavity for compressing the feedstock. Upon compression, there is means provided for frictionally retaining the formed tablet against the inner wall of the cavity. The tablet is thereby retained even after removal of one of the die punches from the cavity.

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Direct compression of tableting feedstock may be used to form low density amorphous compression dosage units. Such low density compression dosage units may be of the type developed by the assignee herein and marketed under the trademark FLASH DOSE®.

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In order to facilitate the formation of low density tablets in a direct compression process, it is only necessary to compact the tableting feedstock held within the die cavity with a low compression force applied by the upper, or upper and lower die punches. In this manner, the resultant tablet is not hardened but remains a dosage unit of relatively low density. However, as the feedstock is compressed with low compression forces to form such a low density tablet, there is a tendency for some or all of the feedstock to adhere or stick to the surfaces of the die punches when the die punch(es) are retracted from the die cavity. This problem is particularly evident where the tableting feedstock contains a high amount of sugar or sugar derivatives. The surfaces of conventional die punches are typically formed of stainless steel and in conventional direct compression techniques, the compression force applied by the punches hardens the tablet to such an extent that feedstock adherence to the punch surfaces is not a problem. However, in forming low density tablets under low compression, the lack of tablet hardening may result in such adherence of feedstock to the die punch surfaces.

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Numerous attempts have been advanced to prevent adherence or sticking of the feedstock to the die punch surfaces. Attempts have been made to form the die punch surfaces of well-known "nonstick" materials in an effort to prevent sticking of the feedstock to the tableting surfaces. The art has attempted to form the die punches with

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nonstick tips or surfaces or to apply coatings or platings to the die punch surfaces which are formed of nonstick materials. Examples of materials which have been employed in an attempt to render the die punches nonstick include PTFE (TEFLON®) coatings and tips as well as a nickel/PTFE plating. However, each of these attempts were not entirely satisfactory in preventing the tabletting feedstock from adhering to the surfaces of the die punches. It has been found that despite using materials which have well-known nonstick characteristics, adherence of the tabletting feedstock, especially the amorphous sugar based product, to the surfaces of the die punches still occurred to some extent in low compression tabletting. The build-up of the adhered feedstock on the die punches occurring over time and in large batch applications, necessitates stopping the tabletting process to clean the die punch surfaces.

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Another problem which is especially prevalent in the use of certain nonstick tips applied to the end of the die punch, is that it is difficult to form a low density tablet having a particular shape or tablet configuration. A desirable configuration for a low density tablet is that having opposed angular chamfered edges rather than edges in the form of a right cylinder so that the edges of the fragile low density tablet are not subjected to fracture, crumbling or deterioration which may adversely affect product appearance and usage. Tablets having chamfered edges have also been found to have lower incidence of friability. However, use of these nonstick tips on the end of die punches prevents the low density tablet from being formed in such a desired configuration.

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Further in those instances where a non-stick surface is applied to a die tip, replacement of the non-stick surface typically necessitates the costly replacement of the entire die tip. Thus, where the non-stick surface becomes worn or eroded during repetitive use or when the eventual build up of feedstock occurs, the die tip itself may be discarded and replaced with a new die tip.

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It is therefore desirable to provide a suitable die punch surface for the tip of the die punch which reduces the tendency for tabletting feedstock to stick thereto in a compression process. Such die punch surfaces would be capable of continuous use in a

manufacturing environment over a long periods of time without build up of residual tableting feedstock thereon. The die punch tip surface should also be readily replaceable when required.

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SUMMARY AND OBJECTS OF THE INVENTION:

It is an object of the present invention to provide an improved die punch for forming compression dosage units, preferably low density tablets from tableting feedstock.

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It is a further object of the present invention to provide an improved die punch tip assembly for use in combination with a die punch where the die punch tip assembly includes a feedstock contacting member which provides for the release of residual feedstock therefrom.

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It is still a further object of the present invention to provide a die punch tip including a feedstock contacting member formed thereon where the feedstock contacting member is formed of resiliently compressible material which provides for the resilient release of feedstock adhered thereto.

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The present invention provides a die punch tip assembly for forming compression tablets from tableting feedstock. The tip assembly includes a tip body having a generally planar element including a first surface for positioning in facing opposition to the tableting feedstock and an opposed second surface. The tip body further includes a stem extending from the second surface of the planar member for securement to a die punch.

25 The feedstock contacting member formed of resiliently compressible material is formed onto the planar element of the tip body. The resiliently compressible material forming the feedstock contacting member covers at least a portion of the second surface of the planar element and is formed into a tablet shaping configuration over the first surface. Due to the compressible nature of the feedstock contacting member, residual feedstock material does not remain thereon during the tablet forming process.

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The present invention also provides a die punch for forming compression formed tablets from tabletting feedstock. The die punch includes a die punch body and a die punch tip removably supported to one end of the die punch body. The die punch tip includes a tip body having a planar element with opposed first and second surfaces. A stem extends from the second surface for attachable insertion into a bore in the one end of the die punch body. The die punch tip further includes a feedstock contacting member formed of resiliently compressible material about the planar element. Resiliently compressible material is formed into a tablet shaping configuration over the first surface.

10 In addition, the present invention provides a method of forming a compression tablet forming tip. A tip body is provided having a planar element and a stem extending from one surface of the planar element. A resiliently compressible material is formed over the planar element covering a least a portion of the one surface and forming a tablet shaping configuration on the other surface.

15 In the preferred embodiments of the present invention, the generally compressible material forming the feedstock contacting member is molded directly over the planar member of the tip. Further, one surface of the planar member may include a raised central portion from which the stem extends. The raised central portion forms an annular surface about the stem. This annular surface remains free from the resiliently compressible material to provide an uncovered surface which is positionable against the one surface of the die punch body. The hardness of the resiliently compressible material is selected so that depending upon the particular feedstock being employed, the feedstock contacting member will have sufficient hardness to form the particular configuration of the tablet yet be sufficiently resiliently compressible to resilient release of the formed tablet without residual feedstock material remaining thereon.

BRIEF DESCRIPTION OF THE DRAWINGS:

30 Figure 1 is a schematic representation of a pair of conventional die punches supported within a die cavity used to compress tabletting feedstock into a tablet.

Figure 2 is a schematic representation of a pair of die punches formed in accordance with the present invention supported within a die cavity used to compress tabletting feedstock into a tablet.

5 Figures 3 and 4 show successive steps of a die punch supported within a die cavity used in accordance with the present invention.

Figures 5, 6 and 7 show, respectively, successive steps employed in forming a die punch of a preferred embodiment of the present invention.

10 Figure 8 is a further embodiment of an improved die punch of the present invention.

15 Figure 9 is an apparatus used to form an improved die punch of the present invention.

20 Figure 10 is a front plan view of a plurality of die punches and cavities for manufacturing tablets from feedstock in accordance with the present invention.

25 Figure 11 is a side elevational showing of a die punch tip body employed in combination with an improved die punch tip assembly of the present invention.

Figure 12 shows a vertical section of the die punch tip assembly of the present invention including the die punch tip body of Figure 11, having formed thereover a resiliently compressible feedstock contacting member.

25 Figure 12A is an enlarged sectional showing of an alternate embodiment of the die punch tip assembly of Figure 12.

30 Figure 13 is a top plan view of the die punch tip assembly of Figure 12.

Figure 14 is a side elevational showing of a die punch which may be used in combination with the die punch tip assembly of Figure 12.

5 Figure 15 shows the lower end of the die punch of Figure 16 for removable attachment with the die punch tip assembly of Figure 12.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS:

10 The present invention provides a unique method and apparatus for preparing compression dosage units, such as tablets, in a die cavity and for releasing the formed tablets

from die punches which form the tablet. The present invention is especially useful for forming rapidly dissolving tablets.

15 The term "tablet" is used herein to mean a unit having two sides, sometimes referred

to as a top and a bottom, and a continuous edge which joins the top and the bottom. The entire mass of the material throughout the tablet is the "volume" of the tablet.

20 The mass of the units prepared in accordance with the present invention is continuous in the sense that the feedstock material used to prepare the units ("tableting feedstock") is prepared in a single compression chamber ("die"), but which may have two different densities. The die cavity can support a pair of opposed compressors, sometimes referred to as "die punches". A first volume is associated with the edge in that it circumscribes the unit and includes the edge surface. A second volume, which is referred 25 to as the "non-edge" portion, is within the edge portion. In the present illustrative example the tableting feedstock is compressed and formed within the die cavity in such a manner that it is readily released after formation without residual feedstock remaining on the die punches.

30 The method and apparatus of this invention are especially useful in making low

density tablets, such as for example rapid dissolving tablets containing saccharides which undergo further curing or processing to form a rigid structure. The term low density is used herein to denote tablets wherein at least 60% and preferably 80% of the volume of the tablet has a density of less than 1.2 grams per cubic centimeter and preferably less than 0.8 grams per cubic centimeter. For preferred embodiments, the apparatus and process of the present invention are used to make high porosity tablets which have a porosity of 0.20 to 0.50 and preferably 0.3 to 0.5. Porosity as used herein is defined as: 5 $1 - (\text{bulk density} \div \text{actual density})$.

10 The method and apparatus of this invention is also useful in making "rapidly dissolving" tablets or other tablets where the feedstock material may "stick" or "cling" to the tablet die punch tip.

15 The non-edge portion of units prepared in accordance with the invention may have a lower density, mass per unit volume, than the edge portion. The non-edge volume density can be less than about 1.2 grams per cubic centimeter, preferably less than 0.8 grams per cubic centimeter, and most preferably not greater than 0.6 grams per cubic centimeter.

20 In certain embodiments the edge portion of tablets prepared according to the invention can have a higher density than the non-edge portion. The edge portion has a density which is at least about 10% greater than the density of the non-edge portion, preferably about 15% greater, and most preferably about 20% greater. Thus, as an example, if the density of the non-edge portion is about 0.6 grams per cubic centimeter, the density of the edge portion is preferably about 0.64 grams per cubic centimeter, 25 preferably about 0.69 grams per cubic centimeter, and most preferably about 0.72 grams per cubic centimeter.

The extent of the edge portion is that amount of volume and surface sufficient to

increase the "strength" of the unit for handling by processing machinery and personnel without deterioration of the unit, "Strength" includes both resistance to unit fracture and surface crumbling, i.e., friability.

5 Tableting feedstock materials that will particularly benefit from the present invention are those which are used to form rapidly disintegrating, or dissolving tablets. Generally these tableting feedstock materials comprise multiparticulate formulations with one or more disintegrating, dissolving or solubilizing excipients. Such excipients have a tendency to adhere to the tableting presses after a short amount of time, creating a costly 10 problem for manufacturers. Examples of such disintegrating tableting feedstock materials can be found in commonly assigned U.S. Patent Nos. 4,855,326; 5,622,719, 5,840,334; 5,464,632; 5,576,014; 3,725,556; 4,517,179 and 5,055,306.

15 In addition to the disintegrating excipients, tableting feedstock materials for rapidly disintegrating tablets may also comprise particulate materials which may also be coated. The particulates can be crystalline, spherical and microparticulate in character. Such microparticulates may also be crystalline or spherical, and coated or uncoated.

20 Additionally, any tableting feedstock materials that comprise materials that have a tendency to stick, clump, or adhere to the tableting die punches should benefit from the resiliently compressible material tipped feedstock contacting members of the present invention.

25 The present invention is directed to improved die punches where the tableting feedstock may be compressed into a tablet and upon disengagement of the die punches from the tableted material residual tableting feedstock is not retained or collected on surfaces of the die punches which contact the feedstock. By eliminating residue tableting feedstock on the die punches, the die punches may be used in an automated repetitive process over a longer time period without need for costly down time due to maintenance 30 and cleaning.

Referring to Figure 1, a schematic representation of a typical die assembly 10 used to form a tablet 13 (Fig. 4) from tableting feedstock 11 (Fig. 3) is shown. A cylindrical die cavity 12 is formed by a cavity wall 14. The cavity wall 14 defines opposed open upper and lower ends 16 and 18 which permit insertable accommodation of an upper die punch 20 and a lower die punch 22 respectively. Each die punch 20, 22 may be formed of stainless steel and includes a generally cylindrical body, and defines opposed tablet shaping end surfaces 24, 26 which are positioned in facing opposition. Die punches 20, 22 are operatively movable toward and away from one another so as to compress tableting feedstock 11 contained with die cavity 12 into a shaped dosage unit such as tablet 13. One or both of the die punches 20 and 22 are subsequently removed from die cavity 12 to permit removal of the formed tablet. The tablet shaping end surfaces 24 and 26 are designed so as to form a particular tablet configuration such as chamfered opposed edges. Such configuration reduces tablet deterioration and friability and results in an aesthetically pleasing tablet shape. in the present embodiment, tablet shaping end surfaces 24, 26 include a perimetrical rim 24a, 26a and a central depression 24b, 26b.

Die assembly 10 may be used to form a low density tablet by applying low compressive forces to the tableting feedstock by opposed die punches 20 and 22. While such low compressive forces are sufficient to shape the tableting feedstock into a low density tablet, it has been found that upon withdrawal of one or more of the punches 20 and 22 from die cavity 16, a certain amount of residual of tableting feedstock is retained on the tablet shaping end surfaces 24 and 26. Such residue is a result of the low compressive forces used to form the low density tablet as well as the amorphous nature of the feedstock material. Furthermore, as mentioned above, preferred materials used to form the feedstock may include sugars or sugar derivatives. The nature of this material also tends to result in feedstock residue remaining on the surfaces of the die punches as they are removed from the die cavity. Feedstock residue remaining on these surfaces may result, in subsequent operations, in improperly formed tablets and require costly down time to clean or change the die apparatus.

With reference to Figure 2, the present invention provides improved die punches in a die assembly where tableting feedstock residue on the tablet shaping end surfaces of the die punches is reduced. Improved die assembly 30 includes a cylindrical die cavity 32 formed by a cavity wall 34. The cavity wall 34 defines opposed upper and lower open ends 36 and 38 which permit insertable accommodation of improved die punches 40 and 42. Die punches 40 and 42 include opposed tablet shaping end surfaces 44 and 46 respectively which are configured as shown in Figure 1 to provide a tablet with opposed chamfered edges. Each tablet shaping end surface 44 and 46 supports an elastomeric feedstock contacting member 50.

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As will be described in further detail hereinbelow, feedstock contacting member 50 is formed of resiliently compressible elastomeric material. The material forming feedstock contacting member 50 as well as its selected thickness permits the feedstock contacting member to compress upon contact with the feedstock material contained in die cavity 32 even under low compression forces.

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Referring now to Figures 3 and 4, a portion of die assembly 30 is depicted with only upper die punch 40 shown for clarity. However, it may be appreciated that lower die punch 42 operates in a similar manner as will be described hereinbelow, but in certain embodiments may not move to the extent that the upper die punch does. Upper die punch 40 moves within die cavity 32 towards the opposed lower die punch (not shown). As upper die punch 40 is moved downwardly as shown in Figure 3 to a tablet forming position, it compresses tableting feedstock 11. Feedstock contacting member 50, due to its resiliently compressible nature, will compress to some extent. Such movement of upper die punch 40 towards the lower die punch will compress feedstock 11 into a tablet configuration with the tablet configuration being defined by the shape of tablet shaping end surface 44 of die punch 40 and the elastomeric feedstock contacting member 50 which is shaped in conformance therewith. Upon such movement of die punch 40 and after application of sufficient compression over sufficient time, die punch 40 is retracted from die cavity 32 through upper end 34 so as to permit removal of the formed low density tablet 13. The

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low density tablet 13 will have the general configuration of tablet shaping end surface 44 as further defined by feedstock contacting member 50. Upon the retraction of die punch 40 from the tablet forming position, the feedstock contacting member 50 will resiliently return to its original uncompressed configuration and, due to this elastic return or rebound, will dislodge any feedstock material remaining in contact with the surface thereof. This resilient rebound effect of the resiliently compressible feedstock contacting member prevents retention or buildup of residual feedstock material thereon. Therefore, upon subsequent cycling of the die punch 40 to form additional tablets 13, feedstock contacting member 50 will present a clean, non-residue bearing surface in position to form the next successive tablet. The present invention takes advantage of the ability of the compressible feedstock contacting member to resiliently return to its uncompressed condition after compression of the feedstock 11 into a tablet 13 so as to discharge or expel any residual uncompressed feedstock material thereon.

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Another benefit of employing a feedstock contacting member of resiliently compressible material is that the compressible nature of the member has a tendency to be less destructive to the components of the feedstock material during formation into a tablet. Feedstock material for tablet formation may contain particulates of active agents which may or may not be coated with protective, enteric or taste-making coatings. These particulates may take the form of crystalline particulates or microparticulates, microparticles, and microspheres. No matter what the form of particulates utilized in the tableting feedstock, it is important that the integrity of the particulates, especially coated particulates, be maintained in the finished tablet. The resiliently compressible material forming the feedstock contacting member of the present invention, due to its resilient compressibility, helps prevent damage to the particulates.

It is within the contemplation of the present invention that any resiliently compressible elastomeric material may be employed as a feedstock contacting member. Such materials should be of sufficient thickness as applied to the tablet shaping end surfaces of the die

punches so as to permit a sufficient degree of resilient compression and elastic return, since the elastic return of the compressible member after tablet formation allows discharge of the residual tabletting feedstock therefrom.

5 The present invention contemplates use of resilient elastomeric materials such as vulcanized rubber (VULCALON™), latex, polyurethane, polyethylene, polyethyleneketone (PEEK) or any other suitable elastomer. As the present invention is designed to form pharmaceutical tablets, it is also desirable to provide a suitable elastomer which is approved

10 for pharmaceutical usage.

Referring now to Figures 5-7, the construction of one preferred embodiment of the die

15 punch of the present invention is described. The feedstock contacting member may be formed from a sheet of medical grade latex material. Such latex material is commonly employed in making latex gloves used in medical applications. An extent 52 of such latex material is shown in Figure 5. As is typical with latex sheet materials such as that used to form latex gloves, one surface 54 thereof typically has a rough surface while the opposed surface 56 has a relatively smooth surface. A segment of latex extent 58 is cut therefrom. Segment 58 is cut to have the general expanse of die punch 40 (Fig. 7) and is slightly larger than the expanse of the tablet shaping end surface, or punch tip 44. The tablet shaping end surface 44 of die punch 40 is cleaned with isopropyl alcohol to remove any debris or impurities. A suitable adhesive 59 is applied to tablet shaping end surface 44 and to the rough surface 54 of segment 58. The segment 58 is then applied to tablet shaping end surface 44 with the smooth surface 56 facing outwardly therefrom. Pressure is applied to the segment 58 against tablet shaping end surface 44 and held there for an appropriate period of time to allow for the adhesive to set. Due to the flexible nature of the latex material forming segment 58, it can be conformed to the particular configuration of tablet shaping end surface 44. As the segment 58 is applied and conformed, any air trapped between the segment and the tablet shaping end surface can be expelled. After the segment 58 has been adhered to tablet shaping end surface 44 to form feedstock

5 contacting member 50, excess latex material extending beyond the expanse of tablet shaping end surface 44 may be trimmed away. While any suitable adhesive may be used to adhere segment 58 to tablet shaping end surface 44 a particular adhesive which has been found to be preferable is an adhesive manufactured and sold by Loctite Corporation under the trade designation SUPER BONDER 495. It is also desirable for the adhesive to be of medical grade for use in pharmaceutical applications. One particular approved medical grade adhesive which may be employed includes Loctite Corporation SUPER BONDER 416.

10 The present invention, as shown in the embodiments in Figures 5-7, provides a feedstock contacting member 50 which is positionable over a tablet shaping end surface 44 to yield a tablet having the desired shape characteristics. As described above, such characteristics include opposed upper and lower edges having a chamfered surface. This embodiment of the present invention achieves this by providing a flexible feedstock contacting member which is applied and conforms to the predetermined shape of the tablet shaping end surface 44 of die punch 40. It is further contemplated that feedstock contacting member may itself be formed into a shape which yields the desired shaped tablet.

15 20 Referring now to Figure 8, further embodiment of the present invention is shown. In Figure 8, a die punch 60 may be employed which is an elongate generally cylindrical member having a lower end 62 which is positioned for insertion into the die cavity (not shown). Lower end 62 has a conventional flat surface which is generally undesirable for forming shaped tablets. A feedstock contacting member or tip 65 may be separately formed and applied to lower end 62 of die punch 60. Tip 65 may be formed by a wide variety of processes including various molding techniques. Numerous compressible elastomeric materials may be so formed to yield a tip of desired configuration. A particular material that is suitable for such molding includes polyurethane. Polyurethane is a material which may be readily molded and has characteristics which are beneficial for use in the present invention. These characteristics include good load bearing properties, high temperature resistance, high temperature properties, moisture resistance and low

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mold shrinkage. Tip 65 can be molded into the shape shown in Figure 8 in a conventional molding process and then applied to lower end 62 of die punch 60 using adhesive securement as above described. Tip 65 thus includes a tablet shaping end surface 66, which is similar to tablet shaping end surface 44 of the die punch 40 and yields a tablet having desired shape characteristics.

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It is further contemplated that tip 65 can be molded and formed directly onto the lower end of die punch 60 in a single operation. With appropriate molding technology, it is contemplated that a tip-forming mold 61 could be constructed where the mold employs die punch 60 as one of the mold parts. Referring to Figure 9, a mold plug 63, having a general configuration of tablet forming end 66 of tip 65 could be constructed so as to mold the polyurethane material between die punch 60 and the mold plug 63. In conventional fashion polyurethane material may be injected into a cavity 61a in mold 61 between punch 60 and plug 63. The tip 65 formed by the injected polyurethane material will take the shape of plug 63 and will be formed directly onto the lower end 62 of die punch 60.

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A further feature of this embodiment of the present invention is that in the molding process, the polyurethane tip 65 could be formed with an embossment (not shown) at depths of between .008 inches and .020 inches. The embossment would be an image (such as indicia) of a desired identification to be placed on the tablet. The resulting embossed tip 65 would have formed thereon the reverse image of the indicia. During the tablet forming process as described above, the tablet would include a raised image of the indicia thereon. This allows the tablet to be formed with product markings directly thereon.

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Referring now to Figure 10, the concepts of the present invention may be employed with a multiple punch die assembly. As shown in Figure 10, a die assembly 70 includes a die housing 72 which supports a plurality of die cavities 74. Upper and lower bases 76 and 78 support a plurality of die punches 80. Each die punch 80 may include a tablet shaping end surface 82 and a feedstock contacting member 86 which may be

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formed in a manner described above with respect to Figures 2-7. In the present illustrative embodiment for clarity, the feedstock contacting member 86 is shown being provided on punches 80 attached to upper base 76. It may be appreciated however that the feedstock contacting members 86 are typically applied both to the upper and lower die punches. Use of die assembly 70 allows multiple tablets 13 to be formed from tableting feedstock in a single operation. Furthermore, use of resilient elastomeric feedstock contacting members 86 permits the die punches to be withdrawn from the die cavity without residual tableting feedstock remaining thereon. This allows the die assembly 70 to be used in a repetitive process over a long period of time without unnecessary down time for cleaning and the like.

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A more preferred embodiment of the present invention is shown with respect to Figures 11-13. As described above with respect to Figure 9, the present invention provides for direct molding of the resiliently compressible tablet forming member directly onto the end of a die punch. While such an assembly serves adequately for its intended purposes, over time there is a tendency for the tablet forming member to wear or erode requiring replacement. In those situations where the tablet forming member is molded directly onto the tip of the die punch, it may be necessary to discard the existing die punch tip and replace it with a new die punch tip. It may be appreciated that complete replacement of the tip of the die punch adds an additional cost to the tablet forming operation.

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A die punch tip may be constructed where a tablet forming member is formed directly onto a die punch tip body so that when the tablet forming member exhibits undesirable wear characteristics, the tablet forming member may be replaced. The used tablet forming member may then be readily removed from the tip body and a new tablet forming member may be formed directly on the tip body for re-use.

Referring to Figures 11-13, a die punch tip assembly of the present invention is shown. A die punch tip assembly 100, shown in Figures 12 and 13 includes a die punch tip body 102 (Figure 11) and a resiliently compressible elastomeric tablet forming

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member 104 formed thereon. Referring specifically to Figure 11, die punch tip body 102 is an elongate member having a planar element 106 at one end thereof. Planar element is generally in a configuration of a disk having opposed upper and lower surfaces 108 and 110 respectively. The shape of planar element 106 is such that it is readily received within a die cavity (not shown) for forming a tablet in conjunction with a second die punch tip (not shown) used in facing opposition thereto. As is described above, the tableting feedstock would be positioned within the die cavity between two opposed die tips and under low compression, the two die tips form a tablet therebetween from the tableting feedstock. Planar element 106 includes a central raised region 112 located above upper surface 108. Raised region 112 is also disk like in shape. Extending from raised central region 112, the die tip body includes an elongate generally cylindrical stem 114. Stem 114 extends centrally from raised region 112 so as to define an annular upper surface 116 of raised region 112 about stem 114. Raised region 112 also defines a depending annular shoulder 118 thereabout.

It is contemplated that the die punch tip body may be formed of a suitably rigid material. In a preferred embodiment the die punch tip is formed of stainless steel. However, it is also contemplated that the die punch tip body may be formed of a suitably rigid polymer such as, for example, a glass filled polycarbonate. As will be described in further detail hereinbelow, forming the die punch tip body of a moldable polymer may result in manufacturing efficiencies when combined with the elastomeric tablet forming member 104.

Referring now more specifically to Figures 12 and 13, the die punch tip assembly 100 is shown. Die punch tip assembly 100 includes tablet forming member 104 formed at the lower end of stem 114 about planar member 106. Tablet forming member 104 is formed from a resiliently compressible elastomeric material of the type described above. In the preferred embodiment of the present invention, the resiliently compressible material employed is polyurethane. As described above, the tablet forming member 104 has generally a disk like configuration defining a lower tablet shaping surface 120 which is designed to compress the tableting feedstock into a desired tablet configuration. The

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tablet forming member 104 is formed onto planar element 106 in a manner where the body 122 of tablet forming member 104 covers the lower surface 110 of planar element 106 and also at least partially covers the upper surface 108 thereof. In a preferred embodiment, the resiliently compressible material is formed over planar element 106 so that the material extends to annular shoulder 118 leaving annular surface 116 of raised region 112 free from elastomeric material. Thus, annular surface 116 of the rigid die punch tip body remains exposed for engagement with the die punch as will be described in further detail hereinbelow.

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The tablet forming member 104 being formed of resiliently compressible elastomeric material, exhibits the desired characteristics described above in that when it is used in a die cavity it will provide for compression of the tableting feedstock into a low density tablet. Upon compaction of the feedstock into a tablet configuration, the resiliently compressible material forming the tablet forming member compresses to a small extent. Once the die punch tip assembly is retracted from the die cavity upon formation of the tablet, the tablet forming member will resiliently return to its original configuration. As described above, this resilient return or rebound serves to dislodge the tablet and any residual feedstock material from the tablet shaping surface 120 of the tablet forming member 104. Also as mentioned above, the resiliently compressible material is non-destructive to the tableting feedstock which is a significant consideration where the tablet feedstock includes drug filled microspheres.

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With particular reference to the embodiment shown in Figures 11-13, it has been found that the resiliently compressible material forming the tablet forming member is selected to have desired hardness as measured on the Shore hardness scale. The hardness of the material is selected so that when functioning as a tablet shaping member, the material has sufficient hardness to compact the tableting feedstock into a particular configuration under low compression forces. However, the material should be sufficiently resiliently compressible so as to have the required elasticity to dislodge the tablet and any residual feedstock from the tablet shaping surface once the tablet is formed. The precise hardness of the material is selected depending upon various factors present in

the manufacture of tablets from feedstock. These factors include a compression density, the characteristics of the tableting material, as well as the size and configuration of the tablet.

5 By way of example, it has been found that in forming tablets from spun tableting feedstock containing Vitamin C mixed with a saccharide based product, a particularly desirable material for the formation of tablet forming member 104 is a thermoplastic polyurethane sold by Bayer Corporation under the trademark TEXIN. The particular thermoplastic polyurethane employed has a hardness value on the Shore hardness scale of from about 75A to about 90A. More preferably, it has been found that a suitable tablet is formed where the hardness of the thermoplastic polyurethane is selected to have a Shore hardness value of from about 80A to about 85A. Specifically, 85A has been found to be most preferable. Thermoplastic polyurethane of this hardness value shows sufficient resilient elastomeric properties so as to allow the tablet and any residual feedstock material to be released from the tablet shaping surface 120 of tablet forming member 104 yet retain sufficient rigid shape characteristics to form the low compression tablet of desired configuration.

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20 It is further contemplated that in the preferred embodiment of the present invention, the tablet forming member 104 is formed directly about the planar element 106 of die punch tip body 102. Such preferred method of forming the tablet forming member is by injection molding the resiliently compressible polyurethane material thereon. Suitable die molds may be provided having the desired shaped characteristics and the die punch tip body 102 may be inserted between the molds in a manner known in the art as insert molding. The thermoplastic polyurethane may be injected into the cavity formed by the die molds and the die tip body to injection mold the material about planar element 106 in the configuration shown in Figure 14. Injection molding is a preferred method, as it is an efficient technique for forming the tablet forming member about the die punch tip body and also allows the tablet shaping surface 120 to be precisely formed. However, 25 while injection molding is described as a preferred method of forming the tablet forming

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member 104 of die punch tip assembly 100, other formation techniques may also be employed.

As mentioned above, while die punch tip body is preferably formed from stainless steel it is contemplated that the die punch tip body may be formed of any suitably rigid material. In fact, it is contemplated that the die punch tip body may be formed from a molded polymer. One such molded polymer which may be employed is glass filled polycarbonate. The die tip punch tip body 102 may be formed in a separate molding operation and subsequently tablet forming member 104 may be molded about planar element 106.

It is further contemplated however that the die punch tip body 102 as well as the tablet forming member 104 may be formed in a single molding operation. When employing a molded polymer for die punch tip body 102, the die punch tip body and the tablet forming member may be formed in a single overmolding process. As is well-known in the art, overmolding allows the co-molding of two different polymers into a single component. Overmolding provides a low cost technique for forming a die punch tip assembly. This cost effective manufacturing method could render the entire die punch tip disposable.

Molding of the tablet forming member 104 directly onto planar element 106 of die punch tip body 102, securely fixes the tablet forming member 104 to the die punch tip body 102. However, it is further contemplated that more secure attachment of tablet forming 104 to die punch tip body may be achieved. As shown in Figure 12A, the planar element 106 of die punch tip body may be modified to include one or more through apertures 125 extending between opposed upper and lower surfaces 108 and 110. The through apertures 125 provide for the accommodation of the resiliently compressible material forming tablet forming member 104 during formation thereof so as to securely position and lock the tablet forming member 104 to the planar member 106 of die punch tip body 102.

Having described the formation of die punch tip assembly 100, its use in combination with a die punch for forming low density tablets from tableting feedstock may be described. Referring to Figures 14 and 15, a conventional die punch 130 is shown. Die punch 130 is typically formed of stainless steel and includes an elongate generally cylindrical die punch body 132. One end of die punch body 132 includes an extending die punch projection 134 which tapers to generally reduced elongate cylindrical configuration. The die punch projection 134 provides for the removable securement of die punch tip assembly 100. In order to provide for such removable securement, the distal end 136 includes an elongate central bore 138 formed therein. The bore 138 is cylindrical in shape having a diameter which provides for the insertion of stem 114 of die punch tip body 102. Die punch projection 134 includes an upper lateral aperture 133 in transverse communication with bore 138. Upper lateral aperture 133 provides a venting passageway to bore 138 to permit the insertion of die punch tip assembly 100 therein as will be described below. The die punch projection 134 also includes a lower lateral aperture 140 in transverse communication with bore 138. Aperture 140 accommodates a set screw 142 which is inserted thereinto to secure die punch tip body 102 within die punch projection 134 in a manner which is well known in the art. Upon proper insertion and location of die punch tip assembly 100 within projection 134 of die punch 130, an annular end surface 137 about bore 138 is placed into contacting engagement with annular surface 116 of raised region 112 of die punch body 102. As annular surface 116 is free from the resiliently compressible material forming tablet forming member 104, the die punch tip assembly may be properly seated and located within die punch projection 134 with annular surface 116 making surface-to-surface contact with the end surface 137.

Once die punch tip assembly 100 is properly located in die punch 130, the die punch may be used in a manner described above in combination with a die cavity and an opposed similarly formed die punch to form a low density tablet from tableting feedstock. The resiliently compressible nature of the tablet forming member 104 allows for release of the formed tablet and any residual feedstock therefrom so that the die punch tip assembly may be repetitively used without need for cleaning and costly down time. However, after repeated use, if the tablet forming member 104 becomes worn or eroded,

the die tip assembly 100 may be removed from the die punch and a replacement die punch tip assembly may be reinserted for subsequent use. The present invention provides manufacturing efficiencies in that the worn die tip assembly need not be completely discarded. The tablet forming member 104 may be stripped from the die punch body 102 and the die punch body may be reused so that a new tablet forming member may be molded thereover. The reusability of the die punch tip body results in a significant cost savings as the tip body is not discarded. This is especially beneficial where the tip body is formed of metal such as stainless steel, where replacement parts may be costly. However, the present invention also contemplates that the entire die punch tip assembly may be discarded where the die punch tip body is formed from a rigid molded polymer such as glass filled polycarbonate. In this instance, it may be more cost efficient to discard the entire die punch tip assembly and replace it, as the cost of manufacturing a subsequent polymer part may be less than the cost of replacing the tablet forming member thereon.

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Various changes to the foregoing described and shown structures would now be evident to those skilled in the art. Accordingly, the particularly disclosed scope of the invention is set forth in the following claims.

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WHAT IS CLAIMED:

1. A die punch tip assembly for forming compression tablets from feedstock comprising:

5 a tip body including a generally planar element;

10 a first surface for positioning in facing opposition to said feedstock and an opposed second surface, said tip body further including a stem extending from said second surface of said planar member for securement to a die punch; and

15 a feedstock contacting member formed of resiliently compressible material formed onto said planar element of said tip body, said contacting member covering at least a portion of said second surface of said element and forming a resilient tablet shaping configuration over said first surface.

2. A die punch tip assembly of claim 1 wherein said feedstock contacting member is molded over said planar element.

15 3. A die punch tip assembly of claim 1 wherein said resiliently compressible material is a polyurethane.

20 4. A die punch tip assembly of claim 2 wherein said planar element includes a through-bore extending between said opposed first end said surfaces for accommodating portions of said feedstock contact member molded thereover for securing said feedstock contacting member to said planar element.

25 5. A die punch tip assembly of claim 1 wherein said planar element includes a raised central portion on said first surface with said stem extending from said raised central portion, said raised central portion forming an annular raised planar surface about said stem and a depending annular shoulder thereabout, said raised planar surface being free of said resiliently compressible material forming said feedstock contacting member.

30 6. A die punch tip assembly of claim 3 wherein said polyurethane has a Shore hardness of about 75A to about 90A.

7. A die punch tip assembly of claim 6 wherein said polyurethane has a Shore hardness of about 80A to about 85A.

5 8. A die punch tip assembly of claim 7 wherein said polyurethane has a Shore hardness of about 85A.

9. A die punch tip assembly of claim 1 wherein said tip body is formed of stainless steel.

10 10. A die punch tip assembly of claim 1 wherein said tip body is formed of glass filled polycarbonate.

11. A die punch tip assembly of claim 10 wherein said tip body and said feedstock contacting members are formed by overmolding.

15 12. A die punch for forming compression formed tablets from tableting feedstock comprising:

an elongate die punch body; and

20 a die punch tip supported to one end of said die punch body, said die punch tip including a tip body having a planar element with opposed first and second surfaces and a stem extending from said second surface for attachable insertion into a bore in said one end of said die punch body;

25 said die punch tip further including a feedstock contacting member formed of resiliently compressible material formed about said planar extent and forming a tablet shaping configuration over said first surface.

13. A die punch of claim 12 wherein said feedstock contacting member is molded about said planar element.

30 14. A die punch of claim 13 wherein said planar element includes a raised central portion on said second surface with said stem extending from said raised central portion,

said raised central portion defining an annular surface about said stem and a depending annular shoulder.

5 15. A die punch of claim 14 wherein said raised annular surface of said planar element is free from said material forming said feedstock contact member, thereby presenting an uncovered surface for engagement with said one end of said die punch body upon said attachable insertion of said stem into said bore.

10 16. A die punch of claim 12 wherein said resiliently compressible material is

17. A die punch of claim 12 wherein said die tip body is formed of stainless steel.

15 18. A die punch of claim 12 wherein said die tip body is formed of glass filled polycarbonate.

20 19. A method of forming a low compression tablet forming tip comprising the steps of:

20 providing a tip body having a planar element and a stem extending from one surface of said planar element; and

25 forming a resiliently compressible elastomer over said planar element, said resiliently compressible elastomer covering at least a portion of said one surface and forming a tablet shaping configuration on said other surface.

25 20. A method of claim 19 wherein said forming step includes:

25 molding said resiliently compressible elastomer about said planar element.

30 21. A method of claim 19 wherein said providing step includes:

30 providing said tip body with a raised central region wherein said stem extends from said raised central region to define an annular surface thereabout; and wherein said forming step further includes:

forming said resiliently compressible elastomer over said one surface with said annular surface being free from said resiliently compressible elastomer.

22. A method of claim 19 wherein said providing step includes:

5 molding said tip body from a glass filled polymer.

23. A method of claim 22 wherein said forming step includes:

molding said resiliently compressible elastomer about said planar extent of said molded tip body.

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24. A method of claim 23 wherein said tip body molding step and said resiliently compressible elastomer molding step includes:

molding said tip body and said resiliently compressible elastomer in a single overmolding process.

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25. A die punch tip for forming low compression tablets from tabletting feedstock comprising:

an elongate rigid stem, said stem being removably attachable to a die punch; and
a tablet forming member formed at one end of said stem, said tablet forming

20 member being formed of resiliently compressible material for resilient engagement with
said tabletting feedstock upon compression into said tablet so as to permit resilient release
of said feedstock from said tablet forming member.

25 26. A die punch tip of claim 25 wherein said resiliently compressible material is
molded to the end of said stem.

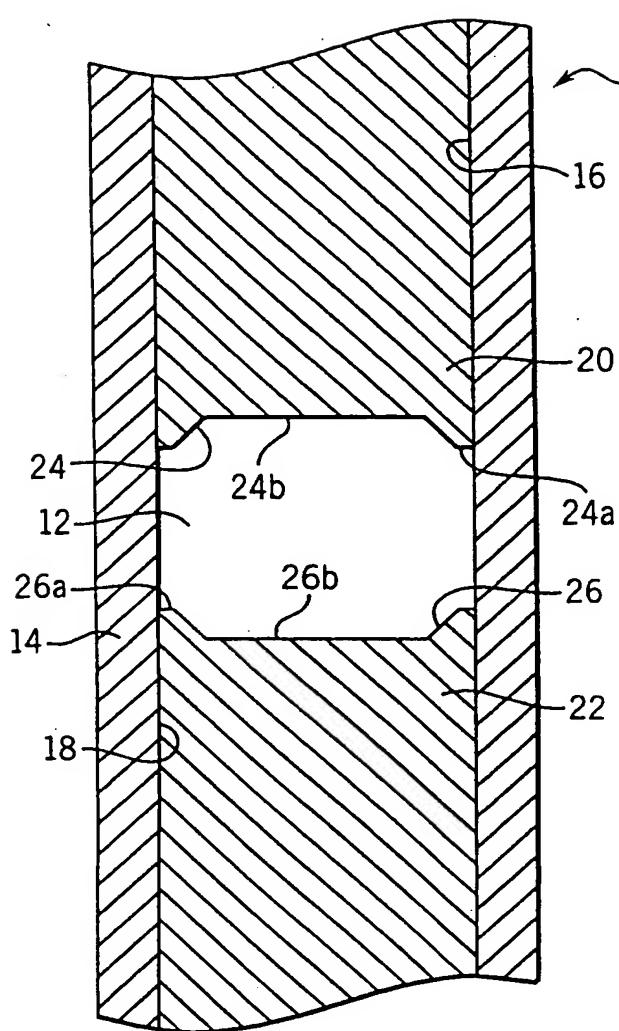


FIG. 1

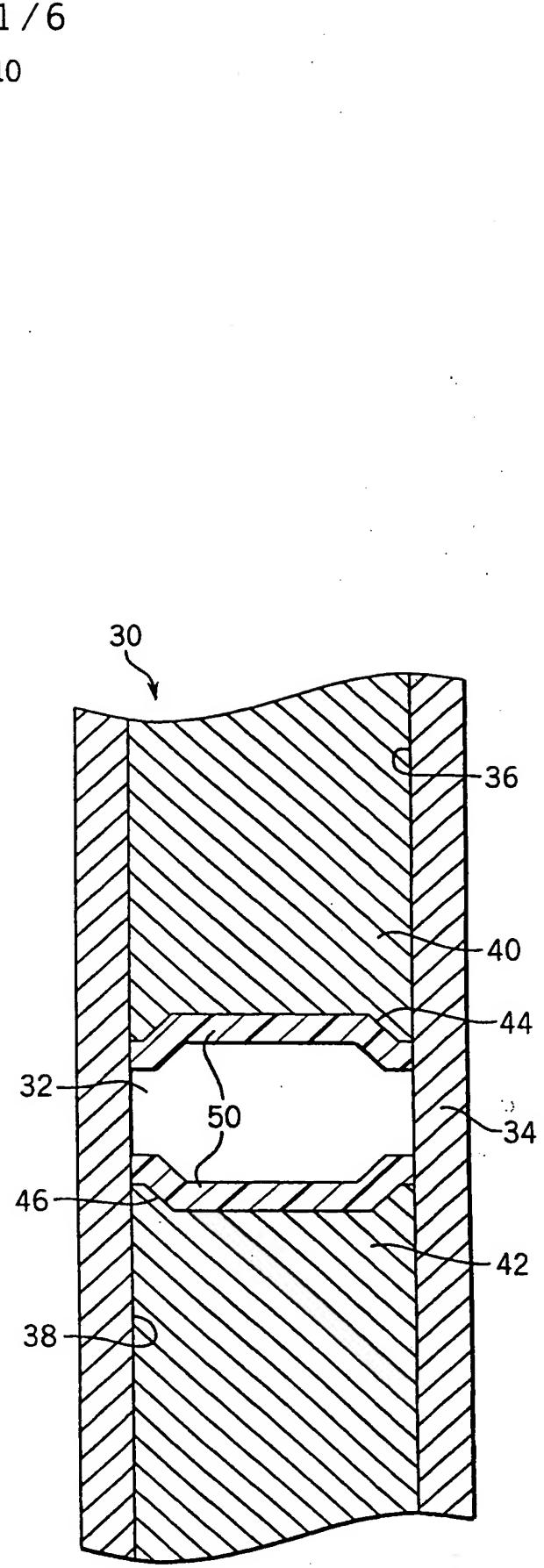


FIG. 2

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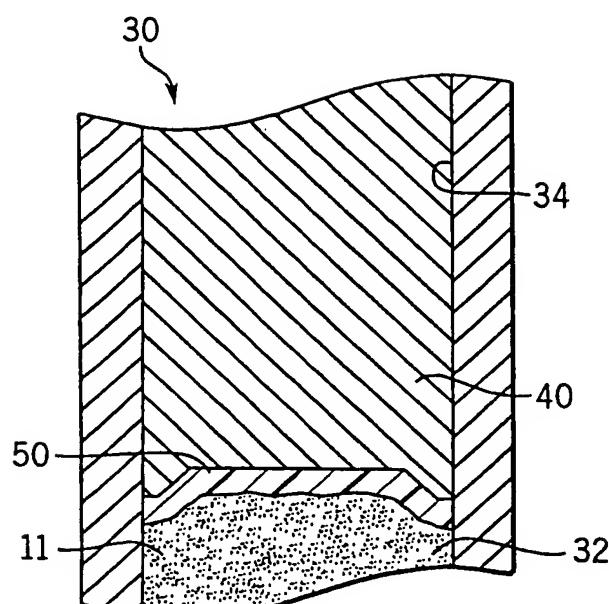


FIG. 3

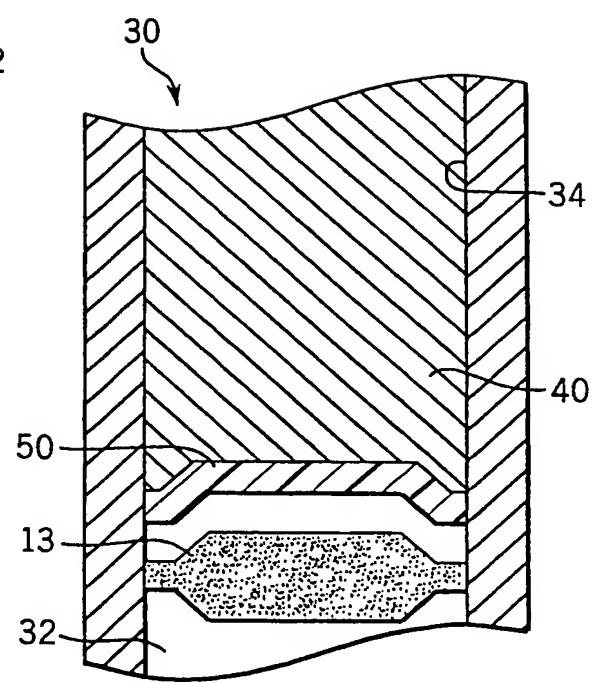


FIG. 4

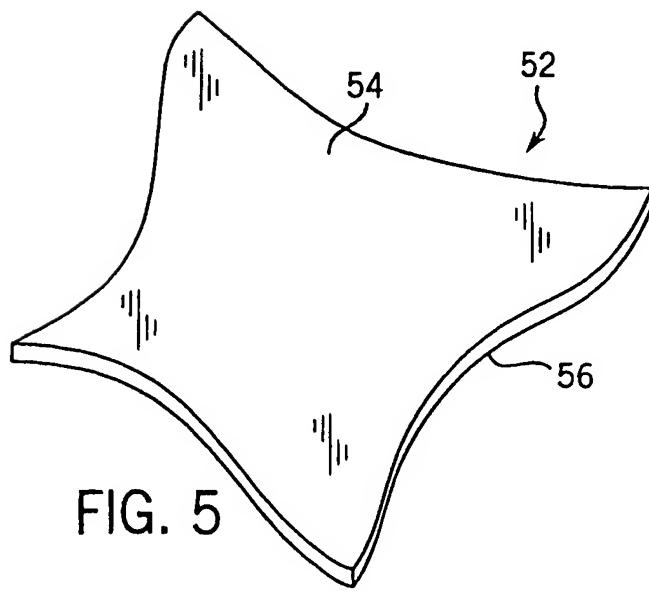


FIG. 5

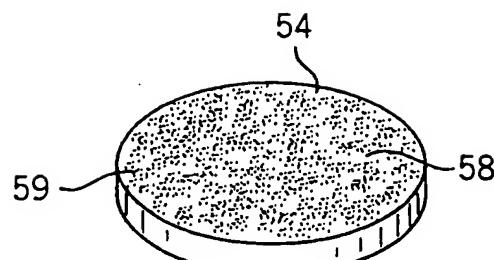


FIG. 6

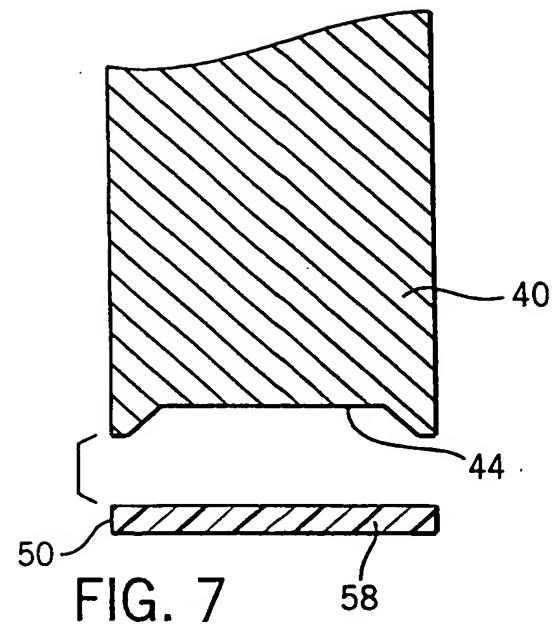


FIG. 7

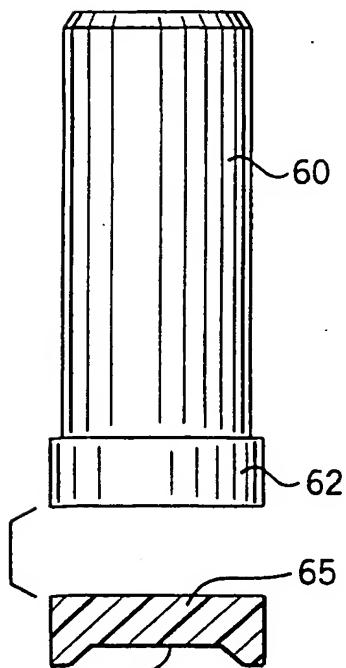


FIG. 8 66

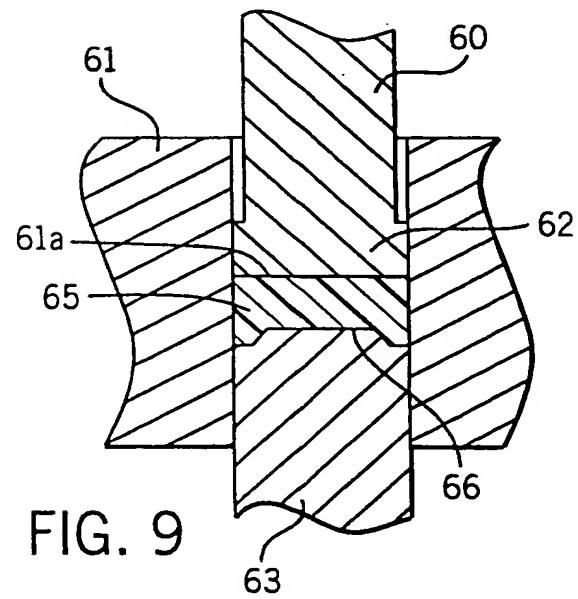


FIG. 9

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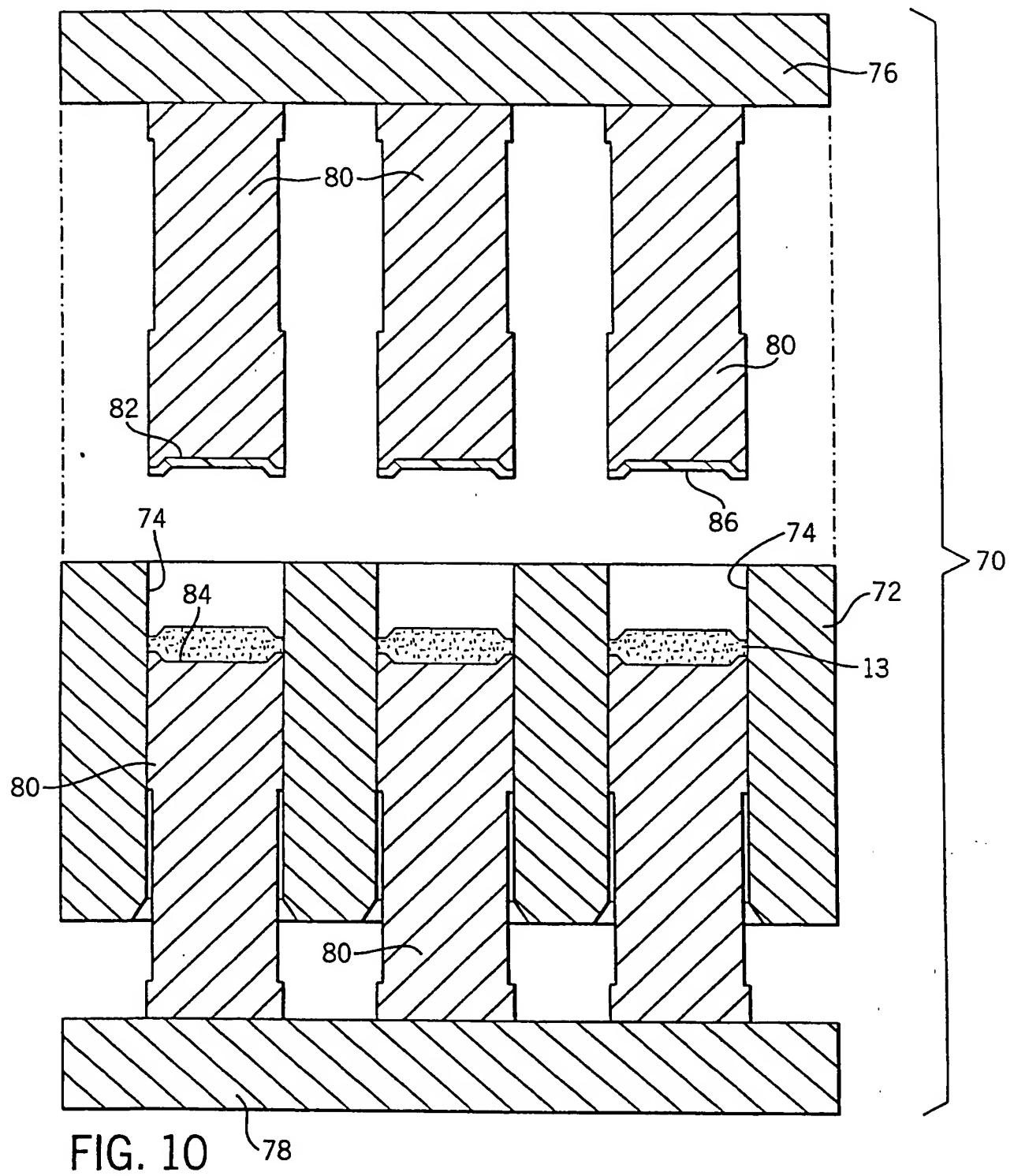
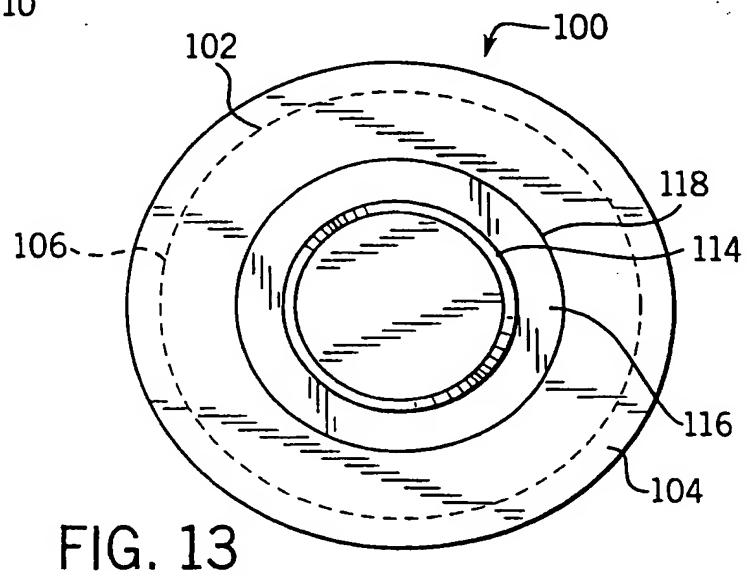
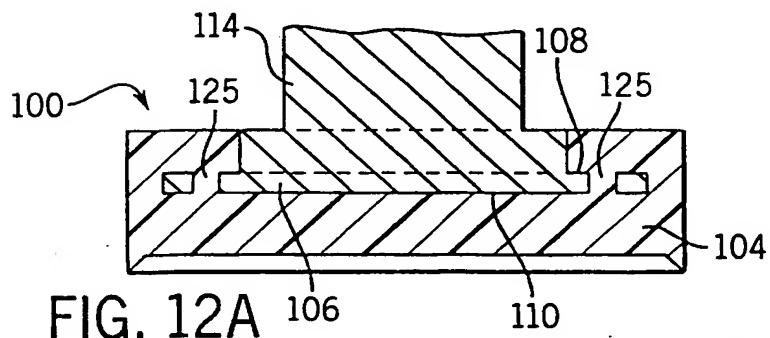
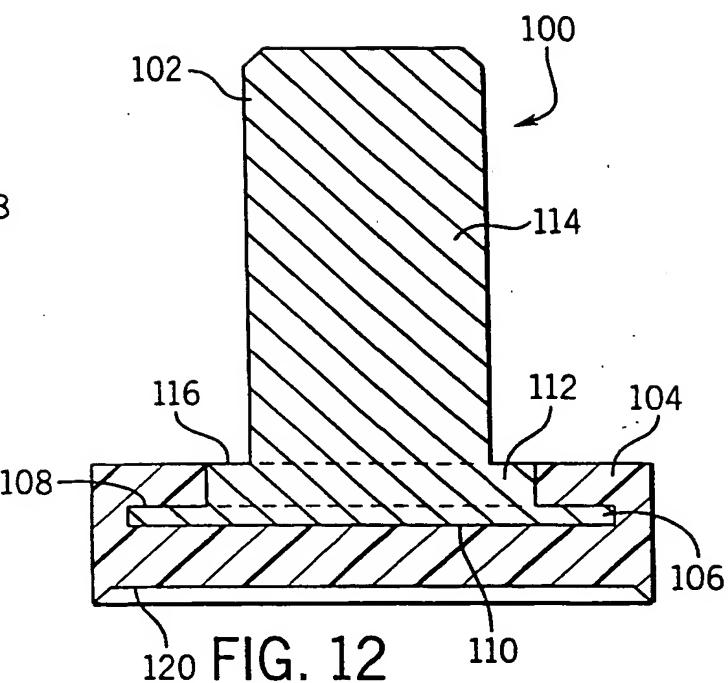
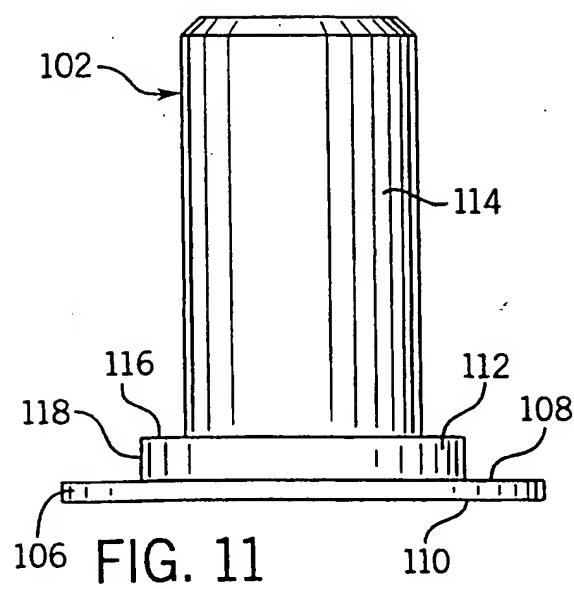
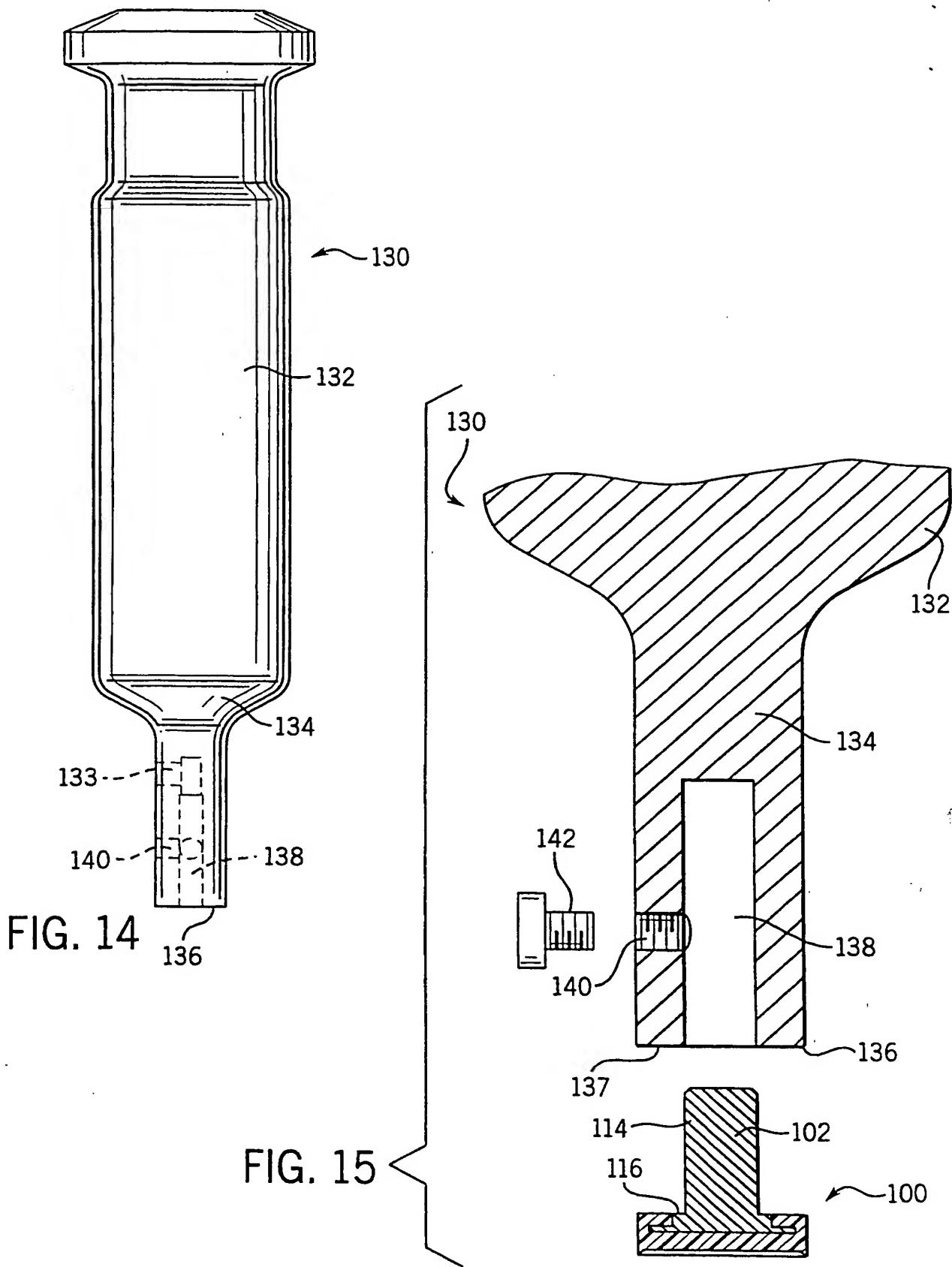


FIG. 10





INTERNATIONAL SEARCH REPORT

Inte onal Application No

PCT/US 99/07496

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 6 B30B15/06 B30B15/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
 IPC 6 B30B B28B B29C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Y	US 3 408 436 A (CUBITT ROBERT BRUCE) 29 October 1968 see column 3, line 45 - line 54; figures ---	2,4,13, 20,22, 23,26

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

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Date of the actual completion of the international search

23 June 1999

Date of mailing of the international search report

01/07/1999

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INTERNATIONAL SEARCH REPORT

Inte
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